REMARKS/ARGUMENTS

The claims have been divided into Groups as follows:

Group I: Claims 1-4 and 8-9, drawn to a method for producing an oral pharmaceutical form with immediate disintegration and active ingredient release even in the mouth; and

Group II: Claims 5-7 and 10-11, drawn to an active ingredient containing powder.

Two elections of species are also required if Group I or II is elected, the elections are as follows:

(1) Election of one of the following anionic active ingredients: anionic analgesic, anionic antirheumatic, or anionic antibiotic.

(2) Election of one corresponding sub-specie of the anionic active ingredient selected above (i.e. anionic analgesic, anionic antirheumatic, or anionic antibiotic) from among those listed in Claim 7.

Applicants elect, with traverse, Group II, Claims 5-7, 10 and 11 (drawn to an active ingredient containing powder), for examination.

Applicants also provisionally elect the following species, for examination purposes only, (1) anionic antirheumatic as the anionic active ingredient and (2) Ibuprofen as the corresponding sub-specie from Claim 7.

Applicants respectfully traverse the Restriction Requirement on the grounds that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctness between the identified groups.

Restriction is only proper if the claims of the restricted groups are independent or patentably distinct and there would be a serious burden placed on the Examiner if restriction is not required (MPEP §803). The burden is on the Examiner to provide reasons and/or examples to support any conclusion in regard to patentable distinction (MPEP §803). Moreover, when citing lack of unity of invention in a national stage application, the Examiner has the burden of explaining why each group lacks unity with each other group specifically describing special technical features in each group (MPEP § 1893.03(d)).

The Office has asserted that Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

> "As disclosed in US 5,158,777, the composition claims 5-7 and 10-11 are anticipated by the prior art (Examples 1 and 3 which disclose a tablet containing ascorbic acid, methacrylic acid copolymer (EUDRAGIT®) and stearic acid). As a result, as currently presented, the instant composition claims do not share a special technical feature with the instant method claims 1-4 and 8-9 and, as such, unity between the above Groups I-II is broken."

However, the Office's interpretation of US 5,158,777 is incorrect. The methacrylic acid copolymers in Examples 1 and 3 are Eudragit L and Eudragit RS (see footnote of the table of Example 1 in column 4). Eudragit L is anionic and Eudragit RS contains quaternary ammonium groups; neither of which contains tertiary amino groups as required by Applicants' claims. Furthermore, Eudragit L and RS of US 5,158,777 are used for enteric coating and delayed released coating respectively. These coating uses are not analogous to Applicants' process. Accordingly, US 5,158,777 does not teach a required element of the present claims and cannot be considered anticipatory of those claims; therefore unity is maintained.

The Office has also asserted that Groups I and II do not relate to a single general inventive concept because they lack the same or corresponding special technical feature for the following reasons: "Group I is drawn to a method for producing a product whereas Group II is drawn to a product. As such, Group I and Group II do not share the same special technical feature".

Applicants point out that 37 C.F.R. § 1.475(b) states in pertinent part:

> "An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
> (2) A product and a process of use of said product;. . ."

In the present case, Groups I and II present a product and a process of use of said product. For example, claim 5 of Group II is drawn to an active ingredient-containing powder and claim 1 of

Group I is drawn to a method of producing a pharmaceutical form which includes mixing of the components of the active-ingredient containing powder. Therefore, Group I can be considered a process of use of the product of Group II. Accordingly, 37 C.F.R. § 1.475(b) applies and unity of invention is maintained.

In addition, the MPEP §806.03 states:

> "Where the claims of an application define the same essential characteristics of a *single* disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are not directed to distinct inventions; rather they are *different definitions of the same disclosed subject matter, varying in breadth or scope of definition.*"

Applicants respectfully submit that the Office has not considered the relationship of the inventions of Groups I and II with respect to 37 C.F.R. § 1.475(b)(2) and MPEP §806.03.

Therefore, in view of the above remarks, the burden necessary according to MPEP § 1893.03(d) to sustain the conclusion that the groups lack of unity of invention has not been met.

Accordingly, and for the reasons presented above, Applicants submit that the Office has failed to meet the burden necessary in order to sustain the requirement for restriction. Applicants therefore request that the requirement for restriction be withdrawn.

Applicants respectfully submit that the above-identified application is now in condition for examination on the merits, and early notice thereof is earnestly solicited.

Respectfully Submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon

Justine M. Wilbur
Registration No. 59,678

Customer Number
22850
Tel. (703) 413-3000
Fax. (703) 413-2220
(OSMMN 08/07)